IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

EXELA PHARMA SCIENCES, LLC, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:12-cv-00469
DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,	)	(LO/JFA)
	)	
UNITED STATES PATENT AND TRADEMARK OFFICE,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Pursuant to Local Rule 7(F)(1), Defendants, through their undersigned counsel, hereby respectfully submit the instant memorandum of law in support of their motion to dismiss in the above-captioned action.

INTRODUCTION

Exela Pharma Sciences, LLC, Exela PharmaSci, Inc., and Exela Holdings, Inc. ("Plaintiffs" or "Exela") seek to manufacture and market a generic drug in the United States that is covered by a patent—U.S. Patent No. 6,992,218 ("'218 patent")—owned by another pharmaceutical company. That company (as well as the licensee of the patent) has filed a patent infringement lawsuit against Plaintiffs in the United States District Court for the District of Delaware seeking to prevent Plaintiffs from manufacturing and marketing their generic drug. As a result, in an effort to invalidate the '218 patent, Plaintiffs in this collateral action challenge a 2003 United States Patent and Trademark Office ("USPTO") decision—as well as the

regulations supporting that decision—to revive the unintentionally abandoned international patent application that eventually issued as the '218 patent. Because this Court lacks subject matter jurisdiction and Plaintiffs fail to state a claim, the case should be dismissed.

First, Plaintiffs' claims are untimely. It is black letter law that the jurisdictional, six-year statute of limitations established in 28 U.S.C. § 2401(a) applies to Administrative Procedure Act ("APA") claims and runs from the date of "final agency action." Here, Plaintiffs' APA claims were filed on April 26, 2012—at least nine years after any "final agency action" related to the USPTO revival decision at issue in this case. Accordingly, Plaintiffs' claims should be dismissed on timeliness grounds.

Second, even if this action is timely, Plaintiffs lack standing because they cannot establish redressability or causation. The underlying patent infringement litigation that forms the basis of this action alleges that Plaintiffs' generic drug infringes on *two* separate patents, only one of which is at issue in this litigation. Thus, even if USPTO's revival decision was improper and the '218 patent was invalidated, Plaintiffs would still be subject to the infringement action, and this Court cannot redress its injury. Moreover, USPTO did not cause Plaintiffs' injury. Rather, a third party not before this Court—*i.e.*, the owner of the '218 patent—caused Plaintiffs' injury by filing a patent infringement suit. Accordingly, for this additional reason, this case should be dismissed for lack of subject matter jurisdiction.

Finally, and most important, Plaintiffs are not entitled to APA review of USPTO's revival decision and regulations. In *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008), the Federal Circuit held that the Patent Act forecloses a defendant in an infringement action from alleging as a defense that the patent-in-suit was improperly revived.

As a result, Plaintiffs cannot circumvent this binding decision and Congress's expressed intent by simply raising the claim in a separate APA action. Moreover, *Aristocrat*'s analysis of the scope of congressional intent with respect to infringement defenses, as well as the Patent Act's plain intent to prohibit third-party participation in *ex parte* revival proceedings, further foreclose Plaintiffs claims pursuant to § 701(a)(1) of the APA. *See Block v. North Dakota*, 461 U.S. 273, 285-86 (1983). Accordingly, those claims should be dismissed.

STATUTORY & REGULATORY BACKGROUND

I. PATENT COOPERATION TREATY PATENT APPLICATION PROCESS

A foreign inventor seeking to apply for a patent in the United States can, *inter alia*, file an international patent application and prosecute the patent in the United States pursuant to the process outlined in the Patent Cooperation Treaty ("PCT"). *See* 35 U.S.C. § 351 *et seq.* The process begins with the filing of an international application and ends (in the case of a favorable outcome for the applicant) with the grant of a number of national and/or regional patents. PCT Applicant Guide at 4, *available at* http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf (last updated June 22, 2012).

In the United States, "[a]n international application [filed pursuant to the PCT] enters the national stage when the applicant has filed the documents and fees required by 35 U.S.C. 371(c) within the period set in [37 C.F.R.] § 1.495." 37 C.F.R. § 1.491; *see also* 35 U.S.C. § 371(f). And consistent with the PCT, § 1.495 provides, *inter alia*, that the international patent applicant must provide "[a] copy of the international application" and "[t]he basic national fee" within

thirty months of the "priority date."[1] 37 C.F.R. § 1.495(b). Failure to meet these requirements results in abandonment of the application. *See* 35 U.S.C. § 371(d).

II. REVIVAL OF ABANDONED PATENTS

A patent application may become abandoned for a variety of reasons. For example, a patent can be expressly abandoned, *see* 37 C.F.R. § 1.138, or it can become abandoned as a result of a failure to prosecute, *see id.* § 1.135. The failure to timely file the documents and fees required by 35 U.S.C. 371(c) to enter the national stage constitutes an example of the latter form of abandonment. *See* 35 U.S.C. § 371(d).

Congress has provided for the revival of abandoned patents under two separate standards. The first provides for the revival of patent applications under a higher cost, but more-easily met "unintentional" delay standard. The second provides for the revival of patent applications under the less expensive, but harder to meet "unavoidable" delay standard. *See* 35 U.S.C. § 41(a)(7). Consistent with § 41(a)(7), 37 C.F.R. § 1.137(b) provides for the revival of unintentionally abandoned patent applications, §1.17(l) and § 1.17(m) establish separate fee provisions for petitions filed under the unintentional and unavoidable delay standards.

III. PATENT VALIDITY CHALLENGES BY GENERIC DRUG MANUFACTURERS SEEKING FDA APPROVAL TO MANUFACTURE AND SELL A PATENTED DRUG

A pharmaceutical company seeking approval to manufacture and sell a new drug must

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[1] "Priority date for the purpose of computing time limits under the Patent Cooperation Treaty is defined in PCT Art. 2 (xi)." *See* 37 C.F.R. § 1.401(f). Under that provision, "'priority date' means, where the international application contains a priority claim, the filing date of the application whose priority is claimed, and, where it does not contain such a claim, the filing date of the international application. Where the international application contains two or more claims, 'priority date' means the filing date of the earliest application whose priority is claimed." PCT Applicant Guide at 4, *available at* http://www.wipo.int/pct/guide/en/gdvol2/pdf/gdvol2.pdf.

file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). Upon filing the NDA, any patents covering the drug, as well as the manufacture and use of the drug, are listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Generic drug manufacturers seeking to manufacture and sell drugs covered by patents listed in the FDA's Orange Book must file an Abbreviated New Drug Application ("ANDA") and submit a certification or statement with respect to each Orange Book-listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)-(viii).

Relevant to the instant case, a generic company may certify, pursuant to paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii), that an Orange Book-listed patent is invalid or that it will not be infringed by the ANDA drug. The filing of such a paragraph IV certification constitutes patent infringement under 35 U.S.C. § 271(e)(2). Accordingly, a pharmaceutical company holding any Orange Book patents covering an ANDA drug has 45 days to sue on these patents in order to invoke a statutorily mandated 30-month stay to delay immediate FDA approval of the generic drug manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). As a defense to infringement, the generic drug manufacturer can challenge the validity of the pharmaceutical company's Orange Book patents covering the ANDA drug.

Section 282 of the Patent Act expressly lists as available defenses "in any action involving the validity or infringement of a patent" failure to satisfy a "condition for patentability," as well as failure to comply with the written description and enablement requirements of § 112 or the reissue requirements of § 251. 35 U.S.C. § 282. The Patent Act sets out the "conditions for patentability" in only three sections: §§ 101, 102, and 103. *Aristocrat Techs. Australia PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008)

(citing *Graham v. John Deere*, 383 U.S. 1, 12 (1966) ("The [1952 Patent] Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness . . . as set out in § 103.")). The U.S. Court of Appeals for the Federal Circuit has held that "Section 282(2), by virtue of its applicability to 'condition[s] for patentability,' relates only to defenses of invalidity for lack of utility and eligibility, novelty, and nonobviousness, and *does not encompass a defense based upon the alleged improper revival of a patent application*." *Aristocrat*, 543 F.3d at 662 (emphasis added).

FACTUAL AND PROCEDURAL BACKGROUND

I. THE '218 PATENT

On June 6, 2000, SCR Pharmatop ("SCR"), a French company, filed French patent application FR 00 07231 for a "new method for obtaining aqueous formulations with active principles susceptible to oxidation and the aqueous solutions thus obtained." *See* Dkt. No. 1 ("Compl.") ¶ 31. A year later, on June 6, 2001, SCR filed in the United States international patent application number PCT/FR01/01749 claiming priority to FR 00 07231. *Id.* ¶ 32. United States patent application number 10/332,060 was the national stage application for PCT/FR01/01749 and ultimately issued in the United States as the '218 patent on January 31, 2006. *Id.*

II. ABANDONMENT AND REVIVAL OF PCT/FR01/01749

SCR was required to fulfill the paperwork and fee requirements of 35 U.S.C. § 371(c) by December 6, 2002—*i.e.*, 30 months from the filing of FR 00 07231—to avoid abandonment of

the PCT/FR01/01749 application. *See* 35 U.S.C. § 371(d); 37 C.F.R. § 1.495(b). SCR failed, however, to make the required submissions by that date, and the application became abandoned. *See* Compl. ¶ 33.

Less than one month later, on or around January 2, 2003, SCR filed a petition pursuant to 37 C.F.R. § 1.137(b) seeking to revive PCT/FR01/01749 as to the United States. *Id.* ¶ 38. In its submission, SCR stated that the entire delay in meeting the national stage requirements was "unintentional." *Id.* On April 25, 2003, USPTO granted SCR's petition, finding that "all requirements under 37 C.F.R. § 1.137(b) ha[d] been met" and requiring the submission of a signed oath or declaration. *See* Gov't Exh. 1. SCR filed the required declaration, and PCT/FR01/01749 was revived.

III. '218 PATENT INFRINGEMENT LITIGATION

Cadence Pharmaceuticals, Inc. ("Cadence")[2] holds NDA No. 022450 for OFIRMEV®, an intravenous formulation of acetaminophen (*i.e.*, Tylenol) available in the United States. *See* Gov't Exh. 2 ¶ 30. The Orange Book lists U.S. Patent No. 6,028,222 ("'222 patent") and the '218 patent for OFIRMEV®. *Id.* ¶ 31; *see also* Compl. ¶ 47. On or around July 7, 2011, Exela Pharma Sciences submitted ANDA No. 20-3092 to the FDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials ("Exela Generic"), as a generic version of OFIRMEV®. *Id.* ¶ 42. Although the '222 patent expires in 2017 and the '218 patent expires in 2021, *see* Compl. ¶

[2]SCR granted an exclusive license to the '218 patent to Bristol-Myers Squibb ("BMS"), and BMS in turn granted Cadence an exclusive sublicense to the '218 patent. *See* Gov't Exh. 2 ¶ 29.

48, Exela submitted paragraph IV certifications with respect to the Orange Book-listed ’218 and ’222 patents, *see* Gov’t Exh. 2 ¶ 44.

Over eight years after USPTO granted SCR’s 37 C.F.R. § 1.137(b) petition to revive PCT/FR01/01749, on August 8, 2011, SCR and filed suit in the United States District Court for the District of Delaware against Exela and other defendants alleging infringement of *both* the’218 patent and the ’222 patent. Cadence and SCR claim that the patents are valid and that the submission of the ANDA application—as well as any commercial manufacture, import, use, offer for sale, or sale of the Exela Generic—constitutes an infringement of the patents-in-suit. *Id.* ¶ 47. As such, SCR and Cadence seek an order that the effective date of approval of Exela’s ANDA be no earlier than the expiration of the patents-in-suit; an injunction prohibiting Exela from engaging in the commercial manufacture, use, offer to sell, sale, or importation of the Exela Generic; and damages should Exela engage in such conduct. *See id.* ¶¶ C, D (Prayer for Relief). That lawsuit is currently in the briefing stage.

IV. EXELA’S § 1.182 PETITION

On November 11, 2011, Exela petitioned USPTO pursuant to 37 C.F.R. § 1.182 to “reconsider and withdraw its petition decision reviving abandoned U.S. patent application no. 10/332,060, which ultimately issued as U.S. Patent No. 6,992,218.” *See* Dkt. No. 1-1 at 1. On February 17, 2012, USPTO issued a Letter stating:

> As a third party to an *ex parte* proceeding, petitioner is not in a position to demand that the USPTO act to vacate a prior decision unless specifically authorized by statute or regulation. In particular, neither the patent statute nor its implementing regulations, confer a right upon a third party to intervene or otherwise challenge the Office’s decision to revive the international application. Information submitted to the Office regarding a patent that is not in reexamination must be consistent with 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. The action requested by the third party here is not specifically authorized by statute or regulation, and the

> communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207. As petitioner lacks standing, the Office will not act as requested.

See Gov't Exh. 3 at 1. Accordingly, USPTO "decline[d] to take any action on petitioner's request" and returned the petition fee. *Id.* at 2. USPTO also determined that the petition would not be made part of record in the application file. *Id.* Exela filed this lawsuit on April 26, 2012.

ARGUMENT

I. GENERAL STANDARDS

Defendants seek dismissal pursuant to both Federal Rule 12(b)(1), for a lack of subject-matter jurisdiction, and Federal Rule 12(b)(6), for failure to state a claim upon which relief can be granted. Initially, Defendants' timeliness and standing defenses implicate the subject matter jurisdiction of this Court under Federal Rule 12(b)(1). *See, e.g., Steel Co. v. Citizens for a Better Environ.*, 523 U.S. 83, 101-02 (1998). Defendants alternatively premise dismissal of USPTO's administrative decisions upon the APA. Lower courts that have confronted such APA issues have treated them jurisdictionally. *See Syntex (USA), Inc. v. USPTO*, 882 F.2d 1570, 1576 (Fed. Cir. 1989) (affirming jurisdictional dismissal); *Hallmark Cards, Inc. v. Lehman*, 959 F. Supp. 539, 542-44 (D.D.C. 1997). The Supreme Court, however, has been less clear. *Compare Block v. Comm. Nut. Inst.*, 467 U.S. 340, 352 n.4 (1984) (considering issues of preclusion pursuant to § 701(a)(1) as jurisdictional) *with Air Courier Conf. v. Am. Postal Workers Union*, 498 U.S. 517, 523 n.3 (1991) (considering similar issues as non-jurisdictional). As such, Defendants seek dismissal pursuant to both Federal Rules 12(b)(1) and 12(b)(6).

A. Federal Rule 12(b)(1)

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) challenges a court's jurisdiction over the subject matter of the suit. *See* Fed. R. Civ. P. 12(b)(1). A Rule 12(b)(1) motion may attack subject matter jurisdiction by asserting that, as a factual matter, the plaintiff cannot meet her burden of establishing a jurisdictional basis for the suit. *See Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982). The plaintiff bears the burden of proving the court's subject matter jurisdiction. *See Evans v. B.F. Perkins Co.*, 166 F. 3d 642, 647 (4th Cir. 1999). In order to evaluate jurisdiction, "[a] trial court may consider evidence by affidavit, depositions or live testimony without converting the proceeding to one for summary judgment." *Id.*

B. Federal Rule 12(b)(6)

In deciding a Rule 12(b)(6) motion, a court must accept as true all well-pled allegations in adjudicating such a motion, but it need not credit allegations that are merely conclusory. *See Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002). In *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the Supreme Court held as follows with respect to the proper standard of review:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted to be true, to "state a claim to relief that is plausible on its face." A claim has factual plausibility when the plaintiff pleads factual content that allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Id. at 1949 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Accordingly, although a court is required to adjudge the legitimacy of the factual averments contained within a complaint against the extant substantive law governing a particular claim,"where the well-pleaded *facts* do not permit the court to infer more than the *mere possibility* of misconduct," the complaint fails. *Id.* at 1950 (emphases added).

II. PLAINTIFFS' CLAIMS ARE UNTIMELY.

Although Plaintiffs' Complaint initially attempts to cast USPTO's decision not to vacate its initial revival of the '218 patent as the basis of this lawsuit, *see* Compl. ¶¶1-2, in fact, the only *actual* relief sought by Plaintiffs concerns the 2003 revival decision itself, as well as USPTO's "rules and regulations allowing for revival of abandoned international patent applications under the 'unintentional' standard," *see id.* ¶¶ 54-77 (Counts I-IV). As such, Plaintiffs' claims are untimely.

"[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues." 28 U.S.C. § 2401(a). This six-year statute of limitations applies to APA actions. *Jersey Heights Neighborhood Ass'n v. Glendening*, 174 F.3d 180, 186 (4th Cir. 1999). An APA action accrues on the date of the "final agency action." *See id.*; *see also Harris v. FAA*, 353 F.3d 1006, 1010 (D.C. Cir. 2004).

Unlike an ordinary statute of limitations, the time limit in "section 2401(a) creates a jurisdictional condition attached to the government's waiver of sovereign immunity." *Hardin v. Jackson*, 625 F.3d 739, 740 n.1 (D.C. Cir. 2010) (internal quotation marks omitted). This condition is unwaivable, proscribes federal jurisdiction, and is not subject to normal exceptions, such as equitable tolling or the continuing violation theory. *See P & V Enters. v. U.S. Army Corps of Eng'rs*, 516 F.3d 1021, 1026-27 (D.C. Cir. 2008); *Ctr. for Biol. Diversity v. Hamilton*, 453 F.3d 1331, 1335-36 (11th Cir. 2006). Strong policy considerations undergird this statute of limitations, *see Wind River Mining Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991) ("The government's interest in finality outweighs a late-comer's desire to protest the agency's

action."), which "must be strictly construed" in favor of the Government, *see Ctr. for Biol. Diversity*, 453 F.3d at 1334; *cf. Kinson v. United States*, 322 F. Supp. 2d 684, 686 (E.D. Va. 2004) (holding that 28 U.S.C. § 2401(b), pertaining to the Federal Tort Claims Act's statute of limitations, "is entitled to strict construction" as a jurisdictional waiver of sovereign immunity).[3]

Under this black letter law, Plaintiffs' challenge to USPTO's decision to revive the PCT/FR01/01749 patent application is untimely. USPTO issued its revival decision on April 25, 2003, *see* Gov't Exh. 1, and Plaintiffs filed this lawsuit on April 26, 2012, over three years after the statute of limitations established in § 2401(a) had passed. Accordingly, this Court lacks subject matter jurisdiction.

Similarly, Plaintiffs' challenge to USPTO's "rules and regulations allowing for revival of abandoned international patent applications under the 'unintentional' standard" is likewise untimely.[4] Consistent with well-settled APA law, the Fourth Circuit has found that "no facial challenge to the language of [a] regulation itself can be raised" where the six-year "statute of limitations [set forth in 28 U.S.C. § 2401(a)] for such an action has passed." *Shipbuilders Council of Am. v. U.S. Coast Guard*, 578 F.3d 234, 245 n.3 (4th Cir. 2009). As such, a

[3]As far as the undersigned counsel is aware, every court of appeals to have directly considered the matter, other than the Ninth Circuit, has found 28 U.S.C. § 2401(a)'s six-year time limit to be a jurisdictional waiver of the United States's sovereign immunity. And even the Ninth Circuit has questioned the viability of its own precedent in light of more recent Supreme Court authority. *See, e.g., Aloe Vera of Am., Inc. v. United States*, 580 F.3d 867, 872 (9th Cir. 2009).

[4]Nowhere in Plaintiffs' Complaint do they identify the precise "rules and regulations" that they seek to strike down. This rather obvious omission in an otherwise detailed Complaint suggests that Plaintiffs do not even know which rules and regulations must be vacated to support their interpretation of 35 U.S.C. § 371(d). In addition to undermining the merits of their interpretation of the statute, this omission could support this Court requiring a more definite statement with respect to this claim. *See* Fed. R. Civ. P. 12(e). But regardless, Defendants will presume for the sake of this motion that Plaintiffs at least challenge 37 C.F.R. § 1.137(b).

pre-enforcement facial challenge to the language of a regulation must be brought within six years of the regulation's promulgation. *See, e.g.*, *Dunn-McCampbell Royalty Interest, Inc. v. Nat'l Park Serv.*, 112 F.3d 1283, 1287 (5th Cir. 1997) ("On a facial challenge to a regulation, the limitations period begins to run when the agency publishes the regulation in the Federal Register." (citations omitted)).

There are only two exceptions to this general rule. *See, e.g.*, *Wind River*, 946 F.2d at 715 (holding that under 28 U.S.C. § 2401(a), a procedural or policy-based facial challenge to a regulation must be brought within six years of the rule's promulgation, but that a challenger may contest a regulation as "exceeding constitutional or statutory authority" later than six years, provided that the challenger "fil[es] a complaint for review of the adverse application of the [agency rule] *to the particular challenger*" (emphasis added)); *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546-47 (D.C. Cir. 1958) (same). First, a plaintiff may bring a facial challenge in accompaniment with an as-applied challenge; that is, "the claimant must show some direct, final agency action involving the particular plaintiff within six years of filing suit." *Dunn*, 112 F.3d at 1287; *see N.L.R.B. Union v. Fed. Labor Relations Auth.*, 834 F.2d 191, 195-96 (D.C. Cir. 1987). Or, a plaintiff may "petition the agency for amendment or rescission of the regulations and appeal the agency's decision," *N.L.R.B. Union*, 834 F.2d at 196, or petition the agency to issue "some new promulgation [that] creates the opportunity for renewed comment and objection," *P & V Enters.*, 516 F.3d at 1024.

Here, in large part because of the ambiguity in Plaintiffs' Complaint with respect to which regulations they seek to challenge, it is unclear whether they seek to characterize their claim as a facial challenge or an as-applied challenge. But regardless, the challenge is untimely.

That is, to the extent Plaintiffs bring a facial challenge, 37 C.F.R. § 1.137(b) was promulgated in 2000, more than six years before Plaintiffs' filed this lawsuit. And to the extent Plaintiffs purport to bring an as-applied challenge, that regulation was never applied *against Plaintiffs*, *see Wind River*, 946 F.2d at 715, and in any event, it was applied in the decision at issue—*i.e.*, the revival decision—nine years ago. Accordingly, the Court also lacks subject matter jurisdiction over Plaintiffs' challenge to USPTO's rules and regulations.

USPTO's Letter response to Plaintiffs' § 1.182 petition does not render these claims timely. In that response, USPTO refused to reconsider its 2003 revival decision because Plaintiffs, as third parties to the *ex parte* revival proceeding, were not authorized by regulation or statute to challenge the revival decision. *See* Gov't Exh. 3 ("The action requested by the third party here is not specifically authorized by statute or regulation, and the communication is not a proper submission under 35 USC § 301, 37 CFR §§ 1.322 or 1.501, or the standards discussed in MPEP § 2207."). Thus, the Letter response does not constitute a timely "final agency action" with respect to revival of the PCT/FR01/01749 patent application. Nor do the regulations that Plaintiffs purport to challenge here have any bearing on USPTO's Letter decision. Rather, the decision at most constitutes "final agency action" regarding USPTO's ability to consider a third party petition regarding a revival decision. And while Plaintiffs may have a timely cause of action challenging that decision, Plaintiffs have raised no such claim here. Accordingly, Plaintiffs claims should be dismissed.

III. PLAINTIFFS LACK STANDING.

Even if Plaintiffs' claims are timely, they should still be dismissed because Plaintiffs lack standing. It is axiomatic that, pursuant to Article III of the United States Constitution, this

Court's jurisdiction extends only to "cases or controversies." U.S. CONST. art. III; *see also Whitmore v. Arkansas*, 495 U.S. 149, 154-55 (1990). The "case or controversy" requirement is satisfied only if a plaintiff has standing—*i.e.*, "the litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). To establish standing, a plaintiff must demonstrate "(1) 'an injury in fact—a harm suffered by the plaintiff that is concrete and actual or imminent, not conjectural or hypothetical'; (2) 'causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant'; and (3) 'redressability—a likelihood that the requested relief will redress the alleged injury.'" *McBurney v. Cuccinelli*, 616 F.3d 393, 402 (4th Cir. 2010) (quoting *Steel Co.*, 523 U.S. at 102-03).

Plaintiffs here do not aver that USPTO's decision to revive the PCT/FR01/01749 patent application—such that the '218 patent is valid—caused an injury-in-fact. Nor could they. The Federal Circuit has repeatedly held that the mere existence of a valid patent alone is insufficient to provide one with standing to challenge the same. *See, e.g.*, *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297-98 (Fed. Cir. 2009) ("[A] mere interest in marketing a product patented to another, without more, does not create a 'definite and concrete' legal conflict."). Instead, one's standing to seek Article III review of a given patent's validity is only triggered after the *patent owner* takes certain definitive action:

> [J]urisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, *without some affirmative act by the patentee*.

SanDisk Corp. v. ST Microelectronics, Inc., 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) (emphasis added). Thus, Plaintiffs premise standing on the existence of the underlying infringement action

that Cadence and SCR—the owner and licensee of the '218 patent, respectively—instituted against Plaintiffs in the United States District Court for the District of Delaware. *See* Compl. ¶¶17-24. This alleged, injury, however, fails under the second and third standing prongs.

A. Plaintiffs Cannot Demonstrate a Redressable Injury That Is Ripe.

To establish redressability for purposes of standing, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 38, 43 (1976)). That is, "a court must determine that there is an available remedy which will have a 'substantial probability' of redressing the plaintiff's injury." *City of Los Angeles v. Lyons*, 461 U.S. 95, 129 n.20 (1983) (Marshall, J., dissenting) (quoting *Warth*, 422 U.S. at 508). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co.*, 523 U.S. at 107. Indeed, the redressability requirement "tends to assure that the legal questions presented to the court will be resolved . . . in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (citations omitted).

Plaintiffs here lack a redressable injury at this time. Plaintiffs premise standing on SCR's and Cadence's patent infringement lawsuit, which, according to Plaintiffs, "seek[s] to preclude Exela from entering the United States market with a generic version of a drug called Ofirmev." Compl. ¶ 19. That is, Plaintiffs allege that had USPTO not improperly revived the PCT/FR01/01749 patent application, they would not be subject to an injunction prohibiting them from marketing the Exela Generic in the United States. *See id.* ¶ 21. However, the patent

infringement suit against Exela—including the requested injunction—is premised not only on the ’218 patent, but also on the ’222 patent. Thus, even if this Court were to determine that Plaintiffs’ claims are timely and that USPTO’s 2003 revival decision was improper such that the ’218 patent was invalidated, the patent infringement suit that allegedly establishes Plaintiffs’ injury-in-fact—as well as the potential for an injunction against the marketing of the Exela Generic in the United States—would remain. *Cf. Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007) (explaining that a single controversy was “created when [the plaintiff] listed its Famvir® patents in the Orange Book, [the defendant] submitted its ANDA certifying all five Famvir® patents under paragraph IV, and [the plaintiff] sued [the defendant] challenging the submission of [the defendant]’s ANDA”). In other words, unless the ’222 patent—the validity of which Plaintiffs do not challenge here—were also invalidated, this Court cannot presently redress Plaintiffs’ injury.

Notwithstanding this glaring redressability problem, Plaintiffs appear to suggest that they have standing because the ’222 patent expires before the ’218 patent. That is, Plaintiffs aver that “[a]bsent the USPTO’s wrongful revival and issuance of the ’218 patent, full generic competition for Ofirmev likely would commence no later than August 5, 2017”—*i.e.*, the date the ’222 patent expires. *See* Compl. ¶ 22. But to the extent Plaintiffs contend that the mere existence of the ’218 patent will prohibit them from marketing the Exela Generic in 2017, as explained *supra*, they cannot establish standing under binding Federal Circuit precedent. *Revolution Eyewear*, 556 F.3d at 1297-98. And to the extent Plaintiffs contend that their alleged current injury—*i.e.*, the threat of an injunction—will be redressed in 2017, the claim is speculative. It is far from “likely” that over five years from now, in the absence of the ’218

patent, Plaintiffs will market the Exela Generic in the United States. *See Lujan*, 504 U.S. at 561. Indeed, Plaintiffs cannot even be sure that they will be in business in 2017, let alone that there will still be a market for the Exela Generic. Accordingly, there is not a "substantial probability" that the relief requested of this Court will redress Plaintiffs' alleged injuries.

Put differently, Plaintiffs' claim is not ripe. *See Prasco v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 n.6 (Fed. Cir. 2008) ("underlying inquiry" into "whether the complained-of-conduct has an immediate and substantial impact" "is the same regardless of whether labeled standing [or] ripeness" (internal quotations omitted)). Ripeness is a justiciability doctrine designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-149 (1967). "Determining whether administrative action is ripe for judicial review requires [a court] to evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Ass'n v. Dept. of Interior*, 538 U.S. 803, 808 (2003).

Here, Plaintiffs cannot demonstrate hardship. *See Caraco Pharm. Lab., Inc. v. Forest Labs., Inc.*, 527 F.3d 1278, 1295 (Fed. Cir. 2008) (finding that a case is not ripe unless the "complained-of conduct has an immediate and substantial impact on the plaintiff" (internal quotations omitted)). Until the '222 patent expires, Plaintiffs cannot market the Exela Generic in the United States regardless of the status of the '218 patent, and any business uncertainty resulting from postponing judicial resolution of the validity of the '218 patent until that time

does not constitute hardship. *See Nat'l Park Hospitality Ass'n*, 538 U.S. at 811. As the Supreme Court explained, if such delay did constitute hardship, "courts would soon be overwhelmed with requests for what essentially would be advisory opinions because most business transactions could be priced more accurately if even a small portion of existing legal uncertainties were resolved," *Id.* at 811. Accordingly, Plaintiffs claims are not ripe and should be dismissed as unredressable and premature.

B. Plaintiffs Cannot Demonstrate That Their Alleged Injury Is Caused by Defendants.

Plaintiffs also fail to satisfy the causation prong of standing. To establish causation, "the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party [*e.g.*, SCR and Cadence, those that brought the underlying infringement suit] not before the court." *Lujan*, 504 U.S. at 560 (quoting *Simon*, 426 U.S. at 41-42) (alterations in original); *see also Mirant Potomac River, LLC v. EPA*, 577 F.2d 223, 226 (4th Cir. 2009) ("An injury sufficient to meet the causation and redressability elements of the standing inquiry must result from the action of the respondent, not from the actions of a third party beyond the court's control."). The Supreme Court has held that in circumstances such as these—where a plaintiff alleges that the government acted unlawfully in an administrative decision regarding *another entity*—constitutional standing "is ordinarily 'substantially more difficult' to establish." *Id.* at 562 (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)). This is so because the element of causation "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Id.*

Plaintiffs' alleged injury—the patent infringement suit in the District of Delaware—relies upon "the independent action of some third party not before the court." *Simon*, 426 U.S. at 41-42. And as a result, the only constitutionally-cognizable injury that Plaintiffs assert in this action was not "caused" by the unlawful action that Plaintiffs seek to have this Court review. *See Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 932 (Fed. Cir. 1991) (holding that a litigant lacks standing when the injury was "not controlled by government action"); *see also Lujan*, 504 U.S. at 562 (holding that a litigant cannot premise "one or more of the essential elements of standing '[] on the unfettered choices made by independent actors not before the court and whose exercise of broad and legitimate discretion the courts cannot presume to predict'" (quoting *ASARCO, Inc. v. Kadish*, 490 U.S. 605, 615 (1989) (plurality opinion))). That is, because USPTO did not file the District of Delaware complaint—again, the only injury identified by Plaintiffs here—USPTO could not have caused Plaintiffs' injury-in-fact. Accordingly, Plaintiffs lack standing, and the case should be dismissed for lack of subject matter jurisdiction.

Judge Ellis's decision in *Centigram Comms. Corp. v. Lehman*, 862 F. Supp. 113 (E.D. Va. 1994)—which Plaintiffs cite in their Complaint, *see* Compl. ¶ 23—is not to the contrary. In a footnote in that decision, the Court stated:

> As an initial matter, the Commissioner has challenged Plaintiff's standing to bring this action. This challenge is not well founded, for Centigram, as an accused infringer, clearly falls within the "zone of interests to be protected or regulated by the statute . . . ."

Id. at 118 n.11 (internal citations omitted).

As an initial matter, this dicta in a footnote authored by another district judge is not binding on this Court. *See, e.g.*, *Threadgill v. Armstrong World Indus., Inc.*, 928 F.2d 1366, 1371 (3d Cir. 1991) ("[I]t is clear that there is no such thing as 'the law of the district.' . . . 'The

doctrine of *stare decisis* does not compel one district court judge to follow the decision of another.'" (quoting *State Farm Mut. Auto Ins. Co. v. Bates*, 542 F. Supp. 807, 816 (N.D. Ga. 1982))). But regardless, *Centigram* does not even address the issue of Plaintiffs' *constitutional* standing. As courts have repeatedly held, a plaintiff must establish both constitutional standing, *see supra*, and "prudential standing"—*i.e.*, that the "interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970) (emphasis added). The *Centigram* footnote clearly addresses only prudential standing—*i.e.*, that the plaintiff there was within the "zone of interests" protected by the Patent Act. *See Centigram*, 862 F. Supp. at 118 n.11. Thus, as Defendants here have not even argued that Plaintiffs fall outside the "zone of interests" or cannot otherwise demonstrate prudential standing, *Centigram* is simply inapposite and does not undermine dismissal in this case.

IV. PLAINTIFFS ARE NOT ENTITLED TO APA REVIEW OF USPTO'S REVIVAL DECISION.

Even if Plaintiffs' claims are timely and Plaintiffs have standing, their challenges to USPTO's revival decision is not subject to APA review and should be dismissed. Although "[t]he APA confers a general cause of action upon persons 'adversely affected or aggrieved by agency action within the meaning of a relevant statute,' [it] withdraws that cause of action to the extent the relevant statute 'preclude[s] judicial review.'" *Block v. Comm. Nut. Inst.*, 467 U.S. 340, 345 (1984) (quoting 5 U.S.C. §§ 701(a)(1); 702). As the Supreme Court explained:

> Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved. Therefore, we must examine this statutory scheme "to determine whether Congress nevertheless foreclosed review to the class to which the [plaintiff] belon[gs]."

Id. at 345-46 (citations omitted) (quoting *Barlow v. Collins*, 397 U.S. 159, 173 (1970) (Brennan, J., concurring)). And as the *Block* Court made clear, whether Congress intended to foreclose judicial review of a given agency action depends upon the "inferences of intent drawn from the statutory scheme *as a whole*." *Id.* at 349 (emphasis added). Where such "congressional intent is 'fairly discernible' in the detail of the legislative scheme, APA review is not available." *Id.* at 351.

Here, Plaintiffs allege that because of the Federal Circuit's binding decision in *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2191 (2009), they must challenge USPTO's revival decision in a separate APA suit rather than as a defense to the underlying infringement suit. *See* Compl. ¶ 24. To the contrary, *Aristocrat* mandates the opposite conclusion—*i.e.*, that Congress intended to preclude all judicial review of USPTO revival decisions at the behest of putative third-party infringers. Moreover, that the Patent Act provides only for *ex parte* revival proceedings further demonstrates that Congress did not intend for those proceedings to be subject to APA suits by third parties. Accordingly, Plaintiffs APA challenge to USPTO's 2003 revival decision should be dismissed.

A. *Aristocrat* Prohibits Judicial Review of Revival Decisions By Third-Party Infringers.

Aristocrat was an infringement action in which the putative infringer alleged (as here) that USPTO erred in reviving the patent-in-suit and sought to have the Court judicially review USPTO's revival order. *See* 543 F.3d at 659-60. The district court in *Aristocrat* held that a putative infringer could assert that USPTO had improperly revived the patent-in-suit as a defense to the infringement action and that it could review the propriety of USPTO's decision under the APA. *See, e.g.*, *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 491 F. Supp. 2d 916,

930-31 (N.D. Cal. 2007), *rev'd*, 543 F.3d 637 (Fed. Cir. 2008). In so holding, the district court rejected application of § 701(a)(1), noting that it had "no basis upon which to find the existence of clear and convincing evidence of Congress's intent to preclude judicial review" of USPTO's revival order. *Id.* at 931.

The Federal Circuit reversed, holding that a claim by a putative infringer that USPTO unlawfully revived a patent in defending against liability was improper. First, the court found that such a claim was not authorized by 35 U.S.C. § 282 as a defense in an action involving the validity or infringement of a patent. *Aristocrat*, 543 F.3d at 660-62. Then, after analyzing the Patent Act in its entirety, the court determined that when Congress "intended to create a defense of invalidity or noninfringement," it "made it clear in various provisions of" the Act, and with respect to the statutory provisions related to revival, Congress failed to evince any such intent. *Id.* at 662. Indeed, the court found that the "objectives" of the Patent Act would be harmed by allowing putative infringers—such as Plaintiffs here—to obtain judicial review of the USPTO's revival decisions:

> If any prosecution irregularity or procedural lapse, however minor, became grist for a later assertion of invalidity, accused infringers would inundate the courts with arguments relating to every minor transgression they could comb from the file wrapper. This deluge would only detract focus from the important legal issues to be resolved – primarily, infringement and invalidity.

Id. at 663. And of particular importance here, the court rejected any role for the APA in such circumstances. *Id.* at 664 ("Under the circumstances of this case, *the APA provides no relief to IGT*." (emphasis added)).

Because *Aristocrat* is binding on this Court, the Federal Circuit's rejection of the district court's attempt to utilize the APA as a mechanism for judicial review is alone sufficient to

require dismissal here. But in any event, its analysis of the scope of congressional intent with respect to infringement defenses further mandates dismissal pursuant to § 701(a)(1). As explained *supra*, the injury on which Plaintiffs premise their standing is the existence of the pending infringement action in the District of Delaware. *See* Compl. ¶¶17-24. As the *Aristocrat* panel held, although Congress articulated several grounds on which an entity such as Plaintiffs could attempt to avoid this injury—including certain USPTO errors (*i.e.*, patent invalidity)—USPTO's purported error in reviving an expired patent is not among them. *See Aristocrat*, 543 F.3d at 662-63. Indeed, as the Federal Circuit held, no provision of the Patent Act provides any "signal[] that Congress has given in other circumstances to indicate that these sections provide a defense to an accused infringer." *Id.* at 663.

Given that Congress clearly intended to preclude a putative infringer from obtaining judicial review of a USPTO revival order as a defense to liability in an infringement action, Plaintiffs here should not be permitted to circumvent congressional intent by simply filing a separate action against USPTO under the APA challenging its revival decision. Put simply, acceptance of Plaintiffs' APA theory would render the deliberate choices Congress made through the Patent Act concerning those defenses available to an entity facing infringement liability (not to mention the Federal Circuit's decision in *Aristocrat*) into a mere pleading exercise. As the Supreme Court has long held, however, "[i]t would require the suspension of disbelief to ascribe to Congress the design to allow its careful and thorough remedial scheme, to be circumvented by artful pleading." *Brown v. GSA*, 425 U.S. 820, 833 (1976); *see Block v. North Dakota*, 461 U.S. 273, 285-86 (1983) (holding that litigants may not utilize the general judicial review provisions of the APA in order to avoid the limitations inherent in other

remedies). As such, the result Plaintiffs seek here—*i.e.*, an end around the Patent Act's limitations on infringement defenses—should be denied. *Cf. Am. Air Par. For. Co. v. United States*, 718 F.2d 1546, 1550 (Fed. Cir. 1983).

B. Third-Party APA Suits Regarding Revival Decisions Are Also Prohibited Because Congress Intended Revival Proceedings to Be *Ex Parte*.

Other aspects of the Patent Act not discussed in *Aristocrat* also render Congress' intent to preclude APA review of USPTO revival decisions by a third party "fairly discernible." In particular, the Supreme Court in *Block* placed significant weight on the fact that the parties seeking judicial review were not entitled to participate in the underlying administrative process:

> Nowhere in the Act, however, is there an express provision for participation by consumers in any proceeding. In a complex scheme of this type, the omission of such a provision is sufficient reason to believe that Congress intended to foreclose consumer participation in the regulatory process.

Block, 467 U.S. at 347. The Patent Act shares these qualities.

Courts have routinely recognized that the Patent Act renders administrative proceedings with respect to patents *ex parte* in nature—*i.e.*, between the patent owner (or applicant, as the case may be) and the agency. The Patent Act thus generally precludes involvement by the putative third-party infringer—*e.g.*, an entity such as Exela that wishes to manufacture and sell a generic version of a drug product on which another entity holds a patent—in the administrative process through which either a patent application is reviewed or issues related to an issued patent are decided. *See Hitachi Metals, Ltd. v. Quigg*, 776 F. Supp. 3, 8 (D.D.C. 1991) (noting the *ex parte* nature of patent prosecution); *Godtfredsen v. Banner*, 503 F. Supp. 642, 646 (D.D.C. 1980) (holding that judicial modification of the statutory ex parte process would "revolutionize patent practice"). Indeed, even before Congress promulgated the most recent incarnation of the Patent

Act (in 1952), the statutes and regulations governing USPTO decision-making in the patent arena have required that administrative proceedings (with particularized and limited exceptions) move forward on an *ex parte* basis. *See, e.g., Williams Mfg. Co. v. United Shoe Mach. Corp.*, 121 F.2d 273, 277 (6th Cir. 1941), *aff'd*, 316 U.S. 364 (1942).

Moreover, Congress has amply demonstrated that when it wants to involve third parties in the administrative review of patent issues, it knows how to do so. In particular, Congress has provided that third parties are entitled to bring certain prior art references to USPTO's attention that might be relevant to a given patent, *see* 35 U.S.C. § 301, and can petition the agency either to undertake *ex parte* reexamination, *see id.* § 302, or *inter partes* reexamination, *see id.* § 311. However, each of these instances in which Congress has expressed its desire to involve third parties in USPTO's administrative process relate to a particularized issue—*i.e.*, the review of an issued patent on *substantive patentability grounds*. And such grounds are not at issue in revival proceedings.

Therefore, that Congress has expressly chosen not to authorize involvement on the part of third parties in USPTO's administrative review of revival decisions demonstrates its intent to preclude APA suits by third parties challenging those decisions. Much like the statutory scheme in *Block*, in the face of specific authorization in other contexts, "the omission of such a provision is sufficient reason to believe that Congress" intended to preclude plaintiff's instant attempt to secure APA review. 467 U.S. at 347. And indeed, there are good reasons not to permit procedural irregularities during prosecution, such as the one at issue here, to provide a basis for invalidity. Once a patent has issued, the "procedural minutiae" of prosecution have little

relevance to the metes and bounds of the patentee's right to exclude. *See Aristocrat*, 543 F.3d at 663; *see also Hallmark Cards*, 959 F. Supp. at 543.

Other courts have held in analogous circumstances that third parties, like Plaintiffs here, cannot seek direct judicial review of *ex parte* decisions by USPTO concerning patents held by other individuals or entities. For example, in *Syntex*, the Federal Circuit, held—in the context of § 701(a)(1)—that "[t]he creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be *unprecedented*," and refused to allow the third party resort to the APA. *Syntex*, 882 F.2d at 1574-75. Similarly, in *Hallmark Cards*, the District of Columbia District Court denied a third party APA review of USPTO's decision to issue a "certificate of correction," 35 U.S.C. § 255, with respect to an already-issued patent. *Hallmark Cards*, 959 F. Supp. at 541-42. After noting that administrative proceedings with respect to a patent owner's request for a certificate of correction were completely *ex parte*, the district court held "that Congress did not intend that third parties have the right to judicial review of Certificates of Correction issued by the PTO." *Id.* at 544. Moreover, the *Hallmark* court also held that the type of administrative action at issue was pertinent to whether Congress had precluded judicial review:

> [I]t would strain credulity to conclude that Congress did not provide for judicial review by third parties of PTO decisions when the PTO conducts a thorough and comprehensive review of a patent in reissue and reexamination proceedings, but intended that third parties have the right to judicial review when the PTO issues Certificates of Correction, which involves a far less intrusive examination of a patent for minor, typographical, and clerical errors.

Id. at 543.

At bottom, administrative proceedings with respect to the revival of expired patents are of a similar ilk, as neither the Patent Act nor USPTO's implementing regulations provide for

"any participation by third parties." *Id.* at 544. Congress expressly included a specific provision in the Patent Act to protect putative infringers in this very context—*i.e.*, USPTO's revival orders—but limited that protection to specific instances (*i.e.*, where the infringer relies upon the expiration of a patent in developing a product). *See* 35 U.S.C. § 41(c)(2). Thus, the "complex scheme" created by the Patent Act precludes APA review of a third party's challenge to USPTO revival decisions.[5]

CONCLUSION

For these reasons, the Court should dismiss this action with prejudice.

Respectfully submitted,

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[5]For all of these reasons, Plaintiffs also are not entitled to APA review of USPTO's revival regulations. Because Plaintiffs cannot challenge USPTO's revival decision, it necessarily follows that they cannot challenge the regulations forming the basis of that decision. Indeed, those regulations can only be applied against patent owners and applicants in revival decisions, and third parties such as Plaintiffs would lack standing to challenge the regulations independent of a revival decision.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 25, 2012, I will file the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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